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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/635,264

08/06/2003

Sung Soo Kim

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06/28/2006

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EXAMINER

ANGELL, JON E

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/635,264

Applicant(s)

KIM ET AL.

Examiner

Jon Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 1,7 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-6 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/6/03</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Action is in response to the communication filed on 4/7/2006.

Claims 1-9 are currently pending in the application and are addressed herein.

#### ***Election/Restrictions***

Applicant's election with traverse of Group II (claims 2-6 and 8) in the reply filed on 4/7/2006 is acknowledged. The traversal is on the ground(s) that (1) the subject matter of Group I is the product that results when the invention of Group II is carried out, and (2) the search for Group II will necessarily include the art related to Group III, and (3) it would not be an undue burden to search and consider Groups I, II and III at the same time. This is not found persuasive because the product of Group I is a polypeptide while Group II is drawn to a product that is an expression vector that expresses cyclophilin, including a cell that overexpresses cyclophilin and a method of making a cell that overexpresses cyclophilin comprising transfecting the expression vector into the cell. Therefore, Groups I and II are drawn to different products and the restriction between these two Groups of products is appropriate for the reasons of record (see the 3/8/06 Action pages 2-3). Furthermore, Group III is drawn to a method for preparing cells comprising culturing the cells in the presence of cyclosporin A. Group II does not require culturing cells in the presence of cyclosporin A. Therefore, the searches required for Group I, II and III are different (i.e., not co-extensive) and the additional searches required for the non-elected Groups are an undue burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

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Claims 1, 7 and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 4/7/2006.

***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 8/6/2003 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "the transplantation" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "the transplantation" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2-6 and 8 rejected under 35 U.S.C. 102(a) as being anticipated by Hong et al.

(FASEB J. August 7, 2002; cited by Applicants in 8/6/03 IDS).

Hong et al. teaches a composition comprising a recombinant expression vector which encodes and expresses wild-type cyclophilin (CypA) which has PPIase activity (e.g., see page 3). Hong et al. also teaches a method for preparing cells comprising transfecting cells (including myoblasts) with an expression vector that encodes and expresses wild-type cyclophilin and selecting cells wherein the cyclophilin is overexpressed and the cells made by this method (e.g., see page 3, page 7, Figure 7, etc.). It is noted that the cells transfected with the vector would overexpress cyclophilin with PPIase activity in an amount sufficient to reduce toxicity induced by cyclosporin A or its analogues (e.g., see Figure 7). Therefore, Hong et al. anticipates the instant claims.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

***Claim Rejections - 35 USC § 102***

Claims 2-6 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,982,082 B1 (Schreiber et al.).

Schreiber teaches a composition comprising a recombinant expression vector which encodes and expresses unmodified cyclophilin (CypA) as well as other modified cyclophilins which are functional (the functional modified cyclophilins would necessarily have PPIase activity) wherein the modified cyclophilins have been modified such that they bind to specific modified cyclosporins, (e.g., see Example 2, columns 40-42, especially column 41 lines 10-55 and column 42, lines 9-11 as well as columns 17-22). Schreiber also teaches a method for preparing cells comprising transfecting cells with the expression vector that encodes and expresses the unmodified cyclophilin (CypA), and selecting cells wherein the unmodified cyclophilin (CypA) is overexpressed (e.g., see Example 2, columns 40-42). It is noted that the cells transfected with the vector would necessarily overexpress cyclophilin in an amount sufficient to reduce toxicity induced by cyclosporin A or its analogues. Although the working examples provided by Schreiber are drawn to Jurkat cells, Schreiber also specifically teaches that it is “especially preferred” that the cells be human cells, and that myoblasts are cells of “particular interest” (e.g., see column 23, line 51 through column 24, line 9; also see column 32, lines 35-55 and column 34, lines 31-34). Therefore, Schreiber anticipates the instant claims.

Applicant is respectfully reminded that MPEP 2112.01 indicates, “Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ

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430, 433 (CCPA 1977). 'When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.'"


### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
JON ANGELL  
PATENT EXAMINER  
Au 1635